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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,058	02/18/2004	John Pafford	MSDI-455/PC263.33	8377
52196	7590	05/03/2010		
MEDTRONIC			EXAMINER	
Attn: Noreen Johnson - IP Legal Department			WILLSE, DAVID H	
2600 Sofamor Danek Drive				
MEMPHIS, TN 38132			ART UNIT	PAPER NUMBER
			3738	
			MAIL DATE	DELIVERY MODE
			05/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/781,058	Applicant(s) PAFFORD ET AL.	
	Examiner David H. Willse	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3-16-2009; 7-23-2009; 12-14-2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 3, 73-75, 77-116 is/are pending in the application.
- 4a) Of the above claim(s) 110-116 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 73-75, 77-102 and 104-109 is/are rejected.
- 7) ☒ Claim(s) 103 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The previous Notices of Non-Responsive Amendments are hereby vacated; the responses listed on the attached first page (PTOL-326) are deemed to be a complete response to the Office action of December 11, 2008.

It is noted that for Information Disclosure Statements, a complete copy (37 CFR § 1.98(a)(2); MPEP § 609.04(a), section II) along with a publication date and other identifying information (37 CFR § 1.98(b)(5); MPEP § 609.04(a), section I) must be presented. Although the Information Disclosure Statement of July 26, 2004, was approved by a previous examiner, said Information Disclosure Statement will not be approved for printing until publication dates are provided for all non-patent literature listed. Moreover, the foreign patent document identified as “U9500308” is erroneous and must be replaced by the correct country code and *publication* number (as opposed to application number). Since Applicant seeks to claim priority to U.S. patent application number 08/603,676, now U.S. patent number 6,423,095 B1, Applicant must present the *publication* number associated with FR 93 11552 (4-1995). The Applicant is requested to provide a list of all references (if any) not cited in the present application or US 6,423,095 B1 but cited in related application serial numbers 10/114,675; 08/740,031; and 08/543,563. The Applicant is also requested to provide copies of all non-patent literature cited in the five earlier related applications in order to expedite prosecution and review.

The disclosure is objected to because of the following: The continuation data at the beginning of the specification is erroneous, as explained in previous Office actions. On page 24, fourth from last line, “curved portion 224” is not indicated in the drawings. On page 25, line 26, “Crock” should be capitalized. On page 37, line 12, “physiological” is misspelled; on lines 20-21, the same reference characters are apparently used to represent different features. On page 39,

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line 4, “in” should be replaced by --is--; on the fifth to last line, “test fixture 318” is not indicated in the drawings. On page 41, line 25, “static” is misspelled. On page 43, lines 5 and 19, “Eppendorf” should be capitalized. On page 45, line 2, “servohydraulic” is misspelled; on line 6, “femur” is misspelled; on line 15, “out” is misspelled; on line 17, --an-- should be inserted after “be”. In claim 83, line 5, it is recommended that “graft” be replaced by --spacer-- or --dowel-- for improved consistency in claim terminology. In claims 104 and 106, line 1 of each, “dowel” should be replaced by --spacer-- or --graft-- (claim 94, line 2). Appropriate correction is required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s) (e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969)).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 3, 73-75, 77-102, and 104-109 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,371,988 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claim limitations are set forth in or would have been obvious

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from the claims of the patent. For example, the cylindrical bone dowel of instant claim 73 would have been inherent from the features set forth in patent claims 15 and 23, and the impregnation with a substantially pure osteogenic factor would have followed from patent claims 25 and 30. Regarding claim 74 and others, threads were quite common in the art at the time of the present invention and would have an obvious variant on the surface types listed in patent claim 16 in order to reduce or eliminate the need for impacting the bone dowel into a disc space. Regarding claim 82 and others, a second osteogenic composition would have been obvious from patent claims 17 and 25 in order to enhance osseointegration of the spacer. The further limitations of claim 83 would have been obvious from patent claim 24 and the matrix of patent claim 18. Regarding claim 87, flattened screw threads were well known in the art and would have been obvious to the ordinary practitioner in order to better stabilize the threaded engagement with bone.

Claim 103 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

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advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday through Thursday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**/David H. Willse/
Primary Examiner
Art Unit 3738**